

## REMARKS

This response is filed in reply to the Office Action mailed March 8, 2007 ("the Action"). Claims 1-21 are pending in the application but stand rejected as being obvious over U.S. Patent Number 5,431,161 to Ryals et al ("Ryals") in view of U.S. Application Publication 2003/0018251 to Solomon ("Solomon") and U.S. Application Publication 2004/0057607 to Breeuwer et al. ("Breeuwer").

### I. Breeuwer

Breeuwer has a filing date of September 19, 2002. Applicant submits herewith a Rule 131 Declaration which Dr. Hamilton, one of the inventors, establishes that the invention of the subject matter of the rejected claims is prior to September 19, 2002, the effective date of Breeuwer. Thus, Applicant respectfully submits that Breeuwer has been removed as a prior art reference to the claimed invention.

### II. Claims 5 and 6

With respect to Claims 5 and 6, the Action concedes that Ryals does not disclose that the system performs myocardial delayed enhancement perfusion imaging and that the screen displays differing locations of the heart with a differing or single dosage of a stress-inducing agent. (Action, p. 4, para. 10). However, the Action states that Breeuwer teaches these features (citing at p. 4 of the Action, to para. 2, 3 and 10 and Figure 1 of Breeuwer) and alleges that one of skill in the art would have modified a system similar to Ryals to include the features of Breeuwer "in order to simultaneous analysis both first pass and late enhancement images as taught by Breeuwer." Action, p. 5, citing para. 6 of Breeuwer. However, as noted above, Applicant has submitted a Rule 131 Declaration, which Applicant respectfully submits removes Breeuwer as a prior art reference. Applicant has amended Claims 5 and 6 into independent form incorporating the subject matter of Claim 1 (their base claim). Applicant respectfully submits that at least Claims 5 and 6 are patentable over the cited prior art, and in condition for allowance, which action is respectfully requested.

### **III. The Obviousness Rejections**

The Action rejects Claims 1-21 as being obvious over Ryals in view of Solomon and further in view of Breeuwer. The Action alleges that Ryals discloses all the features of the claimed invention with respect to Claims 1, 13-16, and 18-21 including obtaining tomographic cine loops of the heart including frames of wall motion images and frames of perfusion images and simultaneously displaying the wall motion loops and the at least one perfusion image loop (citing Figures 8, 13 and Col. 50, lines 3-8, Col. 5, lines 6-25, 35-39 and Col. 53, lines 47-61).

The Action concedes that Ryals (and Breeuwer) fails to expressly disclose using an MRI system for displaying cardiac information of a patient. (Action, p. 5, para. 11). Indeed, Ryals is directed to SPECT (a nuclear camera imaging system). However, the Action alleges that Solomon discloses a CT or MRI cardiac information system that obtains a plurality of cine loops of the heart at a plurality of heart rates including frames of wall motion images. Thus, the Action concludes that it would have been obvious to modify a cardiac system as proposed by Ryals with a late enhancement analysis unit with delayed enhancement myocardial perfusion per Breeuwer and an MRI system that produces MRI cine loops per Solomon so as to not expose the patient to ionizing radiation. Action, p.5. Applicant respectfully disagrees.

First, Applicant notes that Breeuwer has been removed as a reference. Second, Applicant respectfully submits that the claimed MRI-based system of the present invention provides distinct advantages over conventional cardiac evaluation systems or the systems proposed by the cited prior art.

As noted by the Action, Ryals is not directed to MRI systems. Rather, Ryals is directed to nuclear medicine imaging, *e.g.*, Single Photon Emission Computerized Tomography (SPECT). MRI and SPECT systems are very different types of imaging systems. Applicant submits that Ryals is not an enabling disclosure for MRI-based cardiac wall motion and perfusion evaluation systems, as the technical operation and image acquisition features of these two different imaging modalities are very different. Solomon does not remedy these deficiencies; in fact, it teaches away from MRI stress testing as it

merely proposes using a pre-acquired MRI anatomic image.

MRI systems employ certain pulse techniques and breath hold operations and are subject to image distortions and other non-trivial differences that can make stress testing in such a scanner more challenging, particularly where real-time or near-real time image display and acquisition are used (*see, e.g.*, new claims 22 and 23). One of skill in the art would not have modified the SPECT system of Ryals with the mapping and navigation system of Solomon in a manner that would yield the claimed invention.

Solomon states that an MRI image can be previously acquired and used to allow a physician to navigate a diagnostic or therapeutic device in the heart using the previously obtained "road map" image of the heart (para. 12, 13) and superimposing the device on the road map image.

In addition, although Solomon does propose that a loop of previously acquired MRI images can form a movie of a beating heart (para. 12), Applicant was unable to find where Solomon teaches obtaining MRI cine loops at different (stress-induced) heart rates as alleged by the Action at para. 12 (citing para. 13, lines 104 and para. 32). Rather, the cited text in Solomon at para. 32 proposes employing cardiac gating of the cine loop to an EKG cycle during the interventional procedure to synchronize the beating heart in the movie to the EKG in the operating room. The cited text at para. 13 of Solomon merely proposes obtaining a loop of previously acquired MRI images of an entire cardiac cycle to form a movie of the beating heart and that the beating heart movie can be sped up or slowed down according to whether the patient's heart rate increases or decreases as detected by the EKG (para. 13, Solomon). Thus, there is no motivation to combine the teachings of Solomon with Ryals. Applicant submits that one of skill in the art would not combine the references, much less in the manner alleged, and, even combined, Applicant submits that the references would not yield the claimed invention.

The Action then states that the Applicant has not disclosed that using "MRI cine loops" provides an advantage, is used for a particular purpose, or solves a stated problem." The Action concludes that one of skill in the art would have expected the SPECT system of Ryals, modified per Breeuwer, and applicant's invention, to perform equally well with any

type of tomographic technique such as CT and PET and would perform or yield the same function. Action, pp. 5-6. Applicant disagrees.

Applicant respectfully submits that it is improper to modify a prior art reference based on the teachings of the instant invention, as this is impermissible hindsight. Thus, the fact that the Action refers to the teachings of applicant's invention (Action, p. 5, para. 13) with respect to this rejection is improper. Further, Breeuwel has been removed as a prior art reference to the claimed invention.

In response to the allegation that Applicant has not disclosed that the use of MRI cine loops (with perfusion and wall motion images) provides an advantage, is used for a particular purpose, or solves a stated problem, Applicant directs the Examiner's attention to page 8, p. 13, lines 25-33, and p. 14, lines 15-19 which addresses some of the clinical advantages provided by embodiments of the invention. Applicant also respectfully directs the Examiner's attention to Hundley et al., *Utility of Fast Cine Magnetic Resonance Imaging and Display for the Detection of Myocardial Ischemia in Patients Not Well Suited for Second Harmonic Stress Echocardiography*, Circulation, 1999; 100: 1697. A copy of this document is attached for ease of reference (and was cited in a previously submitted Information Disclosure Statement). As discussed in this article, fast cine MRI stress testing can provide safe alternatives for patients not well suited for other conventional evaluation techniques. This article does not teach or suggest simultaneously displaying both wall motion cine loops and the at least one perfusion cine loop.

#### **IV. Related Application**

Out of an abundance of caution, Applicant respectfully notes for the record the existence of a co-pending, co-assigned related patent application, having U.S. patent application serial number 10/629,259 (US 2004-0024306). The Examiner in the related application has rendered a provisional double patenting rejection, which Applicant has argued and disagrees with.

Attorney Docket No. 9151.27  
Application Serial No. 10/628,915  
Filed: July 29, 2003  
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#### **V. New Claims**

Applicant has added new dependent Claims 22-27 directed to the real-time or near real-time display of MRI images. Support for these claims can be found, *inter alia*, at p. 13, lines 9-12, p. 14, lines 5-6, p. 15, lines 26-30, and p. 16, lines 25-26.

#### **CONCLUSION**

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

  
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#### **CERTIFICATION OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on June 8, 2007.

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Rosa Lee Brinson